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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,415	05/16/2001	Falk Fish	FISH4	9137

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BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER
HINES, JANA A

ART UNIT	PAPER NUMBER
1645	8

DATE MAILED: 09/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application N .	Applicant(s)	
	09/763,415	FISH, FALK	
	Examin r	Art Unit	
	Ja-Na A Hines	1645	

-- The MAILING DATE of this communicati n appears on the cover sh et with the correspondence address --

P ri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

1. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

2. The use of the trademark POWERSIGNAL™ and other reagents and apparatus has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for determining the level of glucose and hemoglobin in a sample obtained from a hair follicle, saliva or urine from an individual

comprising: obtaining a sample from the individual; wherein the hair sample is washed and incubated in red cell lysing agent; two aliquots of sample are prepared: sample A is used to determine the level of glucose in the obtained blood or interstitial fluid after it is mixed with glucose oxidase, horseradish peroxidase and luminol and then placed in a luminometer which detects the amount of luminescence while sample B is used to determine the level of hemoglobin in the blood and interstitial fluid obtained from the hair sample as determined by the luminometer and finally the levels of glucose and hemoglobin in the sample are calculated using the net glucose reaction, does not reasonably provide enablement for a method for determining the level of an analyte in the blood of an individual comprising: obtaining a sample from an individual, said sample being a non-blood sample but containing blood components; determining the volume of blood in the obtained sample by measuring the level of a blood component in said sample; determining the amount of glucose in the sample or in the blood cells present in the sample and calculating the level of glucose in the sample. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification, in examples 1-3 teach the determination of the level of glucose and hemoglobin in a sample obtained from a hair follicle, urine or saliva using a luminescent method or lysis method, but the specification does not teach how to determine the level of any analyte in the blood. The specification clearly discloses method steps to determine glucose and hemoglobin levels in a hair, urine or saliva

sample using luminometer or filtration method steps. The claims broadly recite determining the level of any analyte in the blood in any type of non-blood sample and correlating the level of analyte found in the sample to the level of analyte in the blood. However, neither the claims nor the specification recite method steps determining the level of every possible analyte from non-blood samples. Furthermore, there is no teaching that the level of analyte found in the sample correlates to the amount of analyte found in the blood of an individual. Finally, the instant claims fail to recite all of the necessary method steps and reagents required to determine the level of glucose and hemoglobin in the sample. Therefore, the claims are not enabled for a method for determining the level of an analyte in the blood of an individual.

With respect to claim 4, there is no teaching of how to separate fractions of blood and interstitial fluid from each other. Interstitial fluid comprises the same components as blood plasma and blood plasma is separable from red blood cells. The components of plasma include water, proteins, salts, lipids and glucose. As such, neither hemoglobin nor erythrocytes normally pass across the walls of the capillaries and are not expected to be found in either interstitial fluid or blood. See attached documentation from Biology Pages. Thus, there is no teaching of how to determine the level of blood found in an interstitial fluid specimen, since blood is not normally a component of plasma or interstitial fluid. The specification fails to provide guidance on how to determine the level of blood in interstitial fluid, and given the lack of guidance contained in the specification and the unpredictability for determining the level of blood in

interstitial fluid, one skilled in the art could not use the broadly claimed invention without undue experimentation.

Applicants have provided no guidance to enable one of skill in the art how to use, without undue experimentation, method for determining the level of an analyte in the blood of an individual comprising: obtaining a sample from an individual, said sample being a non-blood sample but containing blood components; determining the volume of blood in the obtained sample by measuring the level of a blood component in said sample; determining the amount of glucose in the sample or in the blood cells present in the sample and calculating the level of glucose in the sample. There is no guidance as to what analytes, besides glucose, can be analyzed using this method.

There is no teaching of how to correlate the level of analyte in the sample to the level of analyte in the blood of the sample donor. The art teaches away from using determined glucose levels in saliva to determine the level of analyte in the blood of a donor. Exampled by Ben-Aryeh et al., who teach that salivary glucose concentrations were not significantly correlated with serum glucose, thereby preventing the use of saliva for monitoring blood sugar. Applicants have not shown that the determination of glucose levels in saliva will correlate with the level of analyte in the blood of the donor. Given the lack of guidance contained in the specification, one of skill in the art could not make or use the broad claimed invention without undue experimentation. Thus, one of skill in the art would have to locate de novo steps required for a method of determining the level of any analyte including glucose in the blood of the sample donor.

Moreover, there is no requirement for the use of detectable reagents that would determine the level of glucose or analyte in a sample. Given the lack of guidance contained in the specification and the unpredictability for determining the level of analyte in the blood of an individual based upon determining the amount of analyte in the non-blood sample, one skilled in the art could not use the broadly claimed invention without undue experimentation.

5. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: there is no contact step wherein the sample is contacted with the reagents required to determine the volume or amount of blood or analyte; there is no detection step which detects the volume or amount of blood and analyte; there is no correlation step which correlates determining the amount of analyte and blood in a sample to the level of analyte in the blood of the sample donor. The instant claims recite determining the volume and amount, however the claims fail to positively recite what steps are necessary to determine the volume or amount.

6. Claims 4-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 is unclear as whether the measurements of hemoglobin and glucose were carried out using a sample which comprised both blood and interstitial fluid, since the wording of the claims recites that the measurements were

taken in samples that contained either blood or interstitial fluid. Therefore the claims are unclear and the metes and bounds of the claims cannot be ascertained.

7. Claim 9 recites an instrument "capable of" detect and analyzing a signal, however it is unclear whether the instrument will or will not detect; therefore suggested claim language is "an instrument that detects and analyzes."

It is unclear how to define structures necessary to carry out the measurements. Neither the specification nor claims define what the structures are. Thus, the metes and bounds of the claim language cannot be ascertained.

Prior Art

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Thieme et al., teach saliva assay methods and device. Goldstein et al., teach oral collection devices for immunoassays.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers

for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines
September 17, 2002

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600